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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,521

05/18/2005

Michael R. Emmert-Buck

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EXAMINER

CALAMITA, HEATHER

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

04/02/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/535,521	<b>Applicant(s)</b> EMMERT-BUCK ET AL.	
	<b>Examiner</b> HEATHER G. CALAMITA	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-13 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7 and 9-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 5, 2008, has been entered.

### ***Status of Application, Amendments, and/or Claims***

2. Claims 1-3, 5-13 and 22-24 are pending. Claims 8 and 22-24 are withdrawn as being directed to non-elected subject matter. Claims 1-3, 5-7 and 9-13 are under examination. Any objections and rejections not reiterated below are hereby withdrawn.

### ***Specification***

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1637

Claims 1-3, 5-7 and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kononen et al. (Nature Medicine, 1998).

With regard to claim 1, Kononen et al. teach a method for analyzing the transcriptome of a tissue section comprising analyzing two or more molecular species present in the tissue section while maintaining the 2-dimensional architecture of the molecules within the tissue section, wherein the method comprises (see Figure 1 and Legend):

treating the tissue section with an External Movement Inhibitor device having multiple discrete partitions, wherein the multiple discrete partitions comprise at least one of a plurality of grids or a plurality of wells, whereby each grid or well sequesters molecules corresponding to a specific region or cell type of the tissue section, thereby preserving the 2-dimensional architecture of the molecules present within the tissue section, and determining the location (s) in the tissue section in which the two or more molecular species are present (see Figure 1 and Legend, where the EMI is the adhesive-coated tape sectioning system. This is set up in a grid pattern and the adhesive sequesters molecules corresponding to a specific region of the tissue section and preserves the 2-dimensional architecture of the molecules within the tissue section)

With regard to claim 2, Kononen et al. teach wherein tissue sample obtained from a mammal (see p.844 col. 2 first full paragraph where the tissues is from breast).

With regard to claim 3, Kononen et al. teach the mammal is a human (see the abstract and p.844 col. 2 first full paragraph where the tissues is from breasts of human patients).

With regard to claim 5, Kononen et al. teach the tissue sample is a section from a biopsy (see p. 844 col. 1 first paragraph of the introduction, where the tissue is a core tissue biopsy).

With regard to claim 6, Kononen et al. teach the molecular species are nucleic acid molecules (see the abstract where DNA and RNA targets are disclosed).

Art Unit: 1637

With regard to claim 7, Kononen et al. teach the method additionally comprises incubating the sequestered molecules under conditions sufficient to permit the manipulation of one or more preselected nucleic acid molecules if present in at least one of the plurality of grids or the plurality of wells, while preserving the 2-dimensional architecture of said molecules relative to other molecules of the tissue section (see p. 845 col. 1, where the arrays were subjected to RNAish and see Figure 2 and Legend).

With regard to claim 9, Kononen et al. teach one or more of the preselected nucleic acid molecules are diagnostic of a disease state (see p. 845 col. 1, where the breast cancer array exhibited overexpression of ERBB2 mRNA).

With regard to claim 10, Kononen et al. teach the manipulation is assaying a biomolecule (see p. 845 col. 1, where the breast cancer array exhibited overexpression of ERBB2 mRNA and RNA is the biomolecule assayed).

With regard to claim 11, Kononen et al. teach incubating the sequestered molecules in the plurality of grids or the plurality of wells under conditions sufficient to permit the manipulation of said one or more preselected nucleic acid molecules (see p. 845 col. 1, where the arrays were subjected to RNAish and see Figure 2 and Legend).

With regard to claim 12, Kononen et al. teach the one or more preselected nucleic acid molecules are diagnostic of a disease state (see p. 845 col. 1, where the breast cancer array exhibited overexpression of ERBB2 mRNA).

With regard to claim 13, Kononen et al. teach the manipulation is assaying a biomolecule (see p. 845 col. 1, where the breast cancer array exhibited overexpression of ERBB2 mRNA and RNA is the biomolecule assayed).

### ***Response to Arguments***

5. Applicant's arguments with respect to previously made 102 (e) rejections have been considered but are moot in view of the new 102 (b) rejections

Art Unit: 1637

*Summary*

6. No claims were allowable.

*Correspondence*

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Heather G. Calamita, Ph.D./  
Examiner, Art Unit 1637